REMARKS

Applicants respectfully request entry of the above amendments and reconsideration of the claims.

Amendments

Claims 12-21 are pending, of which claims 12-18, 20, and 21 have been rejected and claim 19 has been allowed. Claims 12, and 18 - 20 have been amended. Support for the amendments in claims 12 and 18-20 can be found in throughout the specification and in claims 1, 10 and 11, as originally filed. The remaining amendments in claims 18 and 20 merely correct typographical errors.

At the outset Applicants like to acknowledge that claim 19 has been allowed and which allowance is appreciated.

Claims Are Definite

Claims 12 -18, 20 and 21 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Examiner it is unclear in claim 12 if the combination of a vessel and a sampling tube are being claimed or just the vessel with the intended usage of a sampling tube. With respect to claim 20, the Examiner asserts that it depends from claim 1 which is cancelled and that the claim does not appear to further limit the vessel in claim 12. Further, according to the Examiner claim 18 refers to a method of claim 15 where claim 15 is drawn to a vessel and the recited process steps do not seem further limit claim 15.

Applicants submit that in the vessel in claim 12 the inert retainer is to hold the pharmaceutical delivery device and provides a passageway to the bottom of the vessel for a sampling tube. The language of claim 12 clearly describes the retainer to have these two characteristics. Accordingly, claim 12 clearly defines the claimed subject matter, which is a vessel containing a retainer and within the

retainer there is provided a passageway for a sampling tube. With respect to claim 20, this claim has been amended to refer to the vessel of claim 12, as opposed to cancelled claim 1, and therefore clearly defines the claimed subject matter. Further, claim 18, as amended, is directed to a method of preparing a vessel **of** claim 15, which is in proper claim format and clearly defines the claimed subject matter.

Accordingly, Applicants submit that claims 12-18, 20, and 21 clearly define the claimed subject matter and withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Claims are Non-obvious

Claims 12-16, 18, and 20-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sinnreich et al (US Patent No. 5,827,984). According to the Examiner Sinnreich et al disclose a device for simulation of dissolution of a pharmaceutical dosage including an inert vessel wall and bottom with fluid medium P, an inert retainer for retaining the pharmaceutical device and providing a passageway to the bottom. The Examiner states that Sinnreich et al lack a teaching of the intended usage of passing a sample tube through the passageway, but such sample tube is capable of being passed through the openings such that it would have been obvious to one of skill in the art to collect a sample by passing the sample tube through the openings. With respect to claim 20, the Examiner states that Sinnreich et al disclose providing plural bases and containers and agitating devices and obviously plural sampling tubes.

Applicants submit that Sinnreich et al do not teach or suggest the claimed vessel, as in independent claim 12, nor the arrangement of such vessels as in the present independent claim 20. In Sinnreich et al Figures 3 and 4 show a beaker (vessel) that is equipped with an intermediate base (column 8, lines 27-28; Fig 3: 26). The intermediate base is being provided as a support for the dosage form with through-openings for the test medium (column 4 lines 40-42; Fig 3: 26). The test medium alone passes through these through-openings when

for example the piston-rod (25) and head (24) (as shown in Figure 3) are moved vertically in the beaker to simulate gastrointestinal conditions. Since the analysis apparatus is to provide "the preconditions for characterizing dosage forms on the basis of their changes in shape and volume" (column 3 lines 41-43), i.e. changes in volume, width or thickness of a dosage form disintegrating and/or being dissolved in the test medium (column 5 lines 8-10), and the intermediate base is a type of sieve plate made from glass or plexiglass (column 8 lines 30-31), the skilled person will understand that the through-openings in the intermediate base need to be small in size to be capable to support the disintegrating and/or dissolving device. In other words the small size of the through-openings is such that the disintegrating dosage form is sufficiently supported on the intermediate base and simultaneously allowing fluid to pass through while at the same time such arrangement prevents a passageway to the vessel bottom for any sampling tube.

Therefore, Sinnreich et al does not teach or suggest a vessel with a retainer for holding a pharmaceutical device and at the same time providing a passageway for a sampling tube to the bottom of the vessel through the opening(s) in the support/retainer as in the presently claimed invention. Moreover, in addition to the fact that one of ordinary skill in the art at the time the invention was made would not be considering that a sampling tube is capable of being passed through the small openings (261), the through-openings as taught in Sinnreich et al are not suitable as a passageway for a sampling tube, which necessarily small diameter does not allow a smooth passage for such sampling tube. Likewise, because the presently claimed single vessel is not taught or suggested, Sinnreich et al certainly do not teach or suggest a plurality of such vessels as in claims 20 and 21.

Accordingly, claims 12-16, 18, 20, and 21 are non-obvious over Sinnreich et al and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Claims 12-18, 20 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Barnwell et al (WO 96/28717). According to the Examiner Barnwell et al disclose a testing vessel with wall and a bottom with a medium and a retainer, which is a mesh or screen with passageways or openings. The Examiner states that Barnwell et al lack a teaching that the openings in the mesh are intended for usage of passing a sample tube through, but such sample tube is capable of being passed through the openings in the screen/mesh and that the mesh material would have to be inert to avoid interference with the testing of the solution. With respect to claims 20 and 21, the Examiner states that the provision of plural vessels with stirring means, sampling and refilling is old and well-known in the ort of dissolution testing such that it would have been obvious to one of ordinary skill in the art to have performed the duplication of parts for simultaneous testing of multiple samples.

Applicants submit that Barnwell does not teach or suggest the claimed vessel, as in independent claim 12, nor the arrangement of such vessels as in the present independent claim 20. In Barnwell a vessel with a means, consisting of an insert, which is provided as a mesh or grille (page 3, lines 26-28) is disclosed. Since the testing vessel is also suitable for testing dissolution of sinking erodible dosage forms (page 3, lines 19-21), which can rest on the top of the insert (page 4, lines 18-19), the skilled person will understand that the openings in the mesh or grille need to be small in size so that the sinking erodible dosage formulation cannot pass through these openings. Considering the small sized openings a person of ordinary skill in the art reading the disclosure of Barnwell would not consider a sampling tube capable of being passed through such small openings in the mesh or grill. Moreover, the openings through the mesh or grill for use in Barnwell are necessarily of such a small diameter which does not allow a smooth passage for a sampling tube.

Therefore, Barnwell does not teach or suggest a vessel with a retainer for holding a pharmaceutical device and at the same time providing a passageway for a sampling tube to the bottom of the vessel through the opening(s) in the

support/retainer as in the presently claimed invention. Likewise, because the presently claimed single vessel is not taught or suggested, Barnwell certainly does not teach or suggest a plurality of such vessels as in claims 20 and 21.

Accordingly, claims 12-18, 20, and 21 are non-obvious over Barnwell et al and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, she is requested to call the undersigned at the number listed below. Applicants respectfully request the issuance of a timely Notice of Allowance in the case.

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Respectfully submitted,

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